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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/625,792 | 07/23/2003 | Marc A. Mandro | 1062/D78 | 9009 |
| 2101 | 7590 | 10/03/2006 | EXAMINER | |
| BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618 | | | LEE, PATRICK J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 2878 | |

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/625,792 | | MANDRO ET AL. | |
| | Examiner | | Art Unit | |
| | Patrick J. Lee | | 2878 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This action is in response to amendment filed September 14, 2006.

Claim Objections

2. Claims 1, 12, & 17 are objected to because of the following informalities:

In each of claims 1, 12, and 17, the use of "therebetween" is inappropriate because it is not a word in the English dictionary.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,452,158 B1 to Whatley et al in view of US 6,645,177 B1 to Shearn.

With respect to claim 1, Whatley et al disclose an apparatus for determining the position of a piston (11) in a cylinder (10) comprising: piston rod (12) as a plunger rod coupled to piston (11) comprising an optically readable marking (16) as an encoding pattern of encoding features; illumination means (17a) as a light source for illuminating the encoded pattern (16); detector array (21) for detecting light from the illuminated encoded pattern and generating a detector signal; and decoding means (18) as a processor for determining the displacement of the plunger rod (12) relative to a fiducial reference position based on the ear (14). The device disclosed by Whatley et al would allow for determination of the position at any point along the piston rod, but does not explicitly disclose the spacing of the encoding features defining spaces such that any two adjacent spaces form a unique sequence. However, Shearn discloses a device in which markers (58) are illustrated to have different sizes as part of the encoding device to determine position. To combine the teachings of Whatley with those of Shearn would have been obvious to one of ordinary skill in the art because such would allow for accurate determination of the position of the plunger. While Shearn discloses the length of features (58) being of a different size along the plunger, to modify the teachings such that the spaces between features (58) were different would have been obvious to one of ordinary skill in the art as a functional equivalent because both methods are capable of accurately determining the position of the plunger.

With respect to claim 2, the modified Whatley et al disclose the use of light reflecting areas for the encoding features, but use of light transmitting areas would have been obvious to one of ordinary skill in the art because such would be functionally equivalent to produce a signal capable of accurately positioning where the plunger rod is.

With respect to claim 3, the modified Whatley et al discloses the use of light reflecting areas (23, 24) for use as the encoding areas.

With respect to claim the modified 4, Whatley et al does not disclose the use of a plurality of slots of enhanced transmission through the plunger rod. However, Shearn discloses the use of a plurality of slots (60) disposed on a plunger rod (42). The use of slots would have been obvious to one of ordinary skill in the art because such would allow for detection of linear motion of the syringe to provide an indication of the amount of fluid remaining in the syringe (see Shearn column 6, lines 52-55).

With respect to claim 5, the modified Whatley et al discloses the slots being displaced at a unique combination of distances (see Shearn figure 6).

With respect to claim 6, the modified Whatley et al does not explicitly disclose the location of the slots as such but such would have been obvious to one of ordinary skill in the art in order to enhance the ability of the device to discriminate to ascertain the position accurately.

With respect to claim 7, the modified Shearn disclose that the characteristic of the reservoir is displacement relative to the fiducial position.

With respect to claim 8, the identified characteristic being a content of a reservoir to which the plunger rod pertains is disclosed as the location of the plunger rod is easily correlated to the amount of substance within the reservoir.

With respect to claim 9, the identified characteristic being the diameter or wall composition of the material would have been obvious to one of ordinary skill in the art because such would allow for the device to prevent error that may result from the use of the wrong plunger while also allowing to factor in the smoothness of the walls in order to determine the rate of dispensing of fluid located within the reservoir.

With respect to claim 10, the modified Whatley et al does not explicitly disclose the use of an optical diffuser, but such would have been obvious to one of ordinary skill in the art in order to ensure that an accurate reading of the encoding features (16) is determined and thus an accurate determination of the position is reached.

With respect to claim 11, the modified Whatley et al disclose the repetition of high and low reflectivity areas (23, 24) along the plunger rod (12).

With respect to claim 12, Whatley et al disclose an apparatus for determining the position of a piston (11) in a cylinder (10) comprising: cylinder (10) as a reservoir having a cylindrical inner volume; piston rod (12) as a plunger rod coupled to piston (11) comprising an optically readable marking (16) as an encoding pattern of encoding features; illumination means (17a) as a light source for illuminating the encoded pattern (16); detector array (21) for detecting light from the illuminated encoded pattern and generating a detector signal; and decoding means (18) as a processor for determining the displacement of the plunger rod (12) relative to a fiducial reference position based

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on the ear (14). The device disclosed by Whatley et al would allow for determination of the position at any point along the piston rod, but does not explicitly disclose the spacing of the encoding features defining spaces such that any two adjacent spaces form a unique sequence. However, Shearn discloses a device in which markers (58) are illustrated to have different sizes as part of the encoding device to determine position. To combine the teachings of Whatley with those of Shearn would have been obvious to one of ordinary skill in the art because such would allow for accurate determination of the position of the plunger. While Shearn discloses the length of features (58) being of a different size along the plunger, to modify the teachings such that the spaces between features (58) were different would have been obvious to one of ordinary skill in the art as a functional equivalent because both methods are capable of accurately determining the position of the plunger.

With respect to claim 13, the modified Whatley et al disclose the use of light reflecting areas for the encoding features, but use of light transmitting areas would have been obvious to one of ordinary skill in the art because such would be functionally equivalent to produce a signal capable of accurately positioning where the plunger rod is.

With respect to claim 14, Whatley et al does not disclose the use of a plurality of slots of enhanced transmission through the plunger rod. However, Shearn discloses the use of a plurality of slots (60) disposed on a plunger rod (42). The use of slots would have been obvious to one of ordinary skill in the art because such would allow for

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detection of linear motion of the syringe to provide an indication of the amount of fluid remaining in the syringe (see Shearn column 6, lines 52-55).

With respect to claim 15, the modified Whatley et al discloses the slots being displaced at a unique combination of distances (see Shearn figure 6).

With respect to claim 16, the identified characteristic being the diameter or wall composition of the material would have been obvious to one of ordinary skill in the art because such would allow for the device to prevent error that may result from the use of the wrong plunger while also allowing to factor in the smoothness of the walls in order to determine the rate of dispensing of fluid located within the reservoir.

With respect to claim 17, Whatley et al disclose an apparatus for determining the position of a piston (11) in a cylinder (10) comprising: piston rod (12) as a plunger rod coupled to piston (11) comprising an optically readable marking (16) as an encoding pattern of encoding features; illumination means (17a) as a light source for illuminating the encoded pattern (16) on the plunger rod (12); detector array (21) for detecting light from the illuminated encoded pattern and generating a detector signal; and decoding means (18) as a processor for determining the displacement of the plunger rod (12) relative to a fiducial reference position based on the ear (14). The device disclosed by Whatley et al would allow for determination of the position at any point along the piston rod, but does not explicitly disclose the spacing of the encoding features defining spaces such that any two adjacent spaces form a unique sequence. However, Shearn discloses a device in which markers (58) are illustrated to have different sizes as part of the encoding device to determine position. To combine the teachings of Whatley with

those of Shearn would have been obvious to one of ordinary skill in the art because such would allow for accurate determination of the position of the plunger. While Shearn discloses the length of features (58) being of a different size along the plunger, to modify the teachings such that the spaces between features (58) were different would have been obvious to one of ordinary skill in the art as a functional equivalent because both methods are capable of accurately determining the position of the plunger.

With respect to claim 18, the modified Whatley et al discloses the use of detector array (21) for imaging the light reflecting from encoding patten (16).

With respect to claim 19, the modified Whatley et al disclose the use of light reflecting areas for the encoding features, but use of light transmitting areas would have been obvious to one of ordinary skill in the art because such would be functionally equivalent to produce a signal capable of accurately positioning where the plunger rod is.

With respect to claim 20, the modified Whatley discloses the storage of the detector array values into a sequence of order N as a step of storing the detector array values in a successive group of n array elements.

Response to Arguments

6. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick J. Lee whose telephone number is (571) 272-2440. The examiner can normally be reached on Monday through Friday, 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Epps can be reached on (571) 272-2328. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patrick J. Lee
Examiner
Art Unit 2878

PJL
September 26, 2006



Stephone B. Allen
Primary Examiner